

REMARKS

Claims 1, 3 – 6, 12 – 16, 22, 24 – 27, 55, 56, and 59 – 69 are pending. In this response, claims 1, 12, 22, 56, and 65 have been amended. Support for the amendments to claims 1 and 56 may be found in the specification at, *e.g.*, at page 21, lines 1 – 9, and in Table 1 on page 31. In addition, support for the amendment to claims 1, 12, 22, and 65, *vis-à-vis* the recitation of “cross-linked,” may be found on page 19, lines 28 – 30. No new matter has been added.

Claim Rejection Under 35 U.S.C. § 112, Second Paragraph Is Moot

Claims 1, 3 – 6, 12 – 16, 22, 24 – 27, 55, 56, and 59 – 69 stand rejected under 35 U.S.C. § 112, second paragraph because the term “about” allegedly renders those claims indefinite. Applicant offers that this rejection is improper, since, as an initial matter, the inclusion of the term “about” does not automatically render the claim indefinite. *See, e.g., Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968). Further, at least one court has held that “[t]he descriptive term ‘about’ . . . does not render a claim indefinite under 35 U.S.C. § 112. Under 35 U.S.C. §112 the term ‘about’ entitles the patentee to a broad interpretation of any range claimed in the patent. ‘About’ is not broad or arbitrary but rather is a flexible term with a meaning similar to ‘approximately’.” *Syntex (U.S.A.) Inc. v. Paragon Optical Inc.*, 7 U.S.P.Q.2d 1001, 1038 (D. Ariz. 1987) (citations omitted). Thus, the term “about” does not render the claims indefinite. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection.

Claim 56 stands rejected as allegedly being indefinite because it “not only fails to further limit the subject matter of a previous claim 1, but it broadens the scope of claim 1.” Office Action, page 3. Applicant has amended claims 1 and 56 such that claim 1 recites a range of local anesthetic contained in the patch and claim 56 recites a specific amount of local anesthetic that falls within the range recited in claim 1. Reconsideration and withdrawal of the rejection are respectfully requested.

Claim Rejections Under 35 U.S.C. § 103 Over Cassell, Cassell In View Of Keusch, Or Fischer In View Of Keusch Should Be Withdrawn

Claims 1, 3 – 6, 12 – 16, 22, 24 – 27, 55, 56, and 59 – 69 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,383,511 (“Cassell”) or over Cassell in view of U.S. Patent No. 5,143,071 (“Keusch”) or over U.S. Patent No. 6,455,066 (“Fischer”) in view of Keusch.

The present application was filed after November 29, 1999. Consequently, the present application may take advantage of the provisions afforded by 35 U.S.C. § 103(c). Pursuant to *Manual of Patent Examination and Procedure* (MPEP) §§ 706.02(l)(1) and 706.02(l)(2), therefore, Applicant submits herewith a Statement Concerning Common Ownership, which shows that the present invention, Cassell and Fischer, were all commonly owned by, and subject to assignment to, EpiCept Corporation at the time the present invention was made. The showing of common ownership disqualifies Cassell and Fischer as prior art references under 35 U.S.C. § 103. The rejections enunciated on pages 3 – 8 of the Office Action, therefore, can not stand. Applicant respectfully requests reconsideration and withdrawal of the rejection.

The Rejection of Claims Under 35 U.S.C. § 103 Over Cooke In View of Keusch Should Be Withdrawn

Claims 1, 3 – 6, 12 – 16, 22, 24 – 27, 55, 56, and 59 – 69 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 6,469,227 (“Cooke”) in view of Keusch.

It is well settled that the Patent Office bears the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. *In re Deuel*, 51 F.3d 1552, 1557 (Fed. Cir. 1995); *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, the Patent Office must first show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition. Second, it must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant’s disclosure. Third, the Patent Office must show that the prior art teaches or suggests all the claim limitations. *Manual of Patent Examination and Procedure* (MPEP) § 2143; *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). These criteria must be satisfied with factual and objective evidence found in the prior art: an examiner’s conclusory statement cannot form a basis for a *prima facie* case of obviousness. *In re Sang-Su Lee*, 277 F.3d 1338, 1343-4 (Fed. Cir. 2002).

Thus, when conducting an analysis under 35 U.S.C. § 103(a), an Examiner “must step backward in time and into the shoes worn by the hypothetical ‘person of ordinary skill in the art’ when the invention was unknown and just before it was made.” MPEP §2142. This is important, as “impermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art.” *Id.* Consequently, when

determining whether or not a claimed invention is obvious, one must cast his/her “mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field.” *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999).

According to the Examiner, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use Keusch’s cross-linked polyvinylpyrrolidone (PVP) hydrogel, which comprises, *e.g.*, 5 – 35% by weight PVP, in Cooke’s patch for anesthetizing the skin. Office Action, page 9. Applicant respectfully disagrees with the Examiner.

First, there is nothing in the cited art that would suggest to those of ordinary skill in the art that they should use Keusch’s cross-linked PVP hydrogel with Cooke’s non-occlusive adhesive skin patch—much less that if they tried, that it would have a reasonable expectation of actually working (*vide infra*).

The adhesive in Cooke’s patch comprises a polymer that may be chosen from a long list of “suitable” polymers that include PVP. But, Cooke states that the preferred polymer is karaya. *Id.* at column 6, line 63 to column 7, line 12. Moreover, all of Cooke’s examples use adhesives resulting from the combination of karaya, algin, a polyacrylamide and/or an acrylic ester copolymer. *Id.* column 12, line 1 to column 16, line 60. By using polymers in his adhesive *other than* PVP, Cooke actually *teaches away* from the presently claimed invention. Further, aside from the instant disclosure, there is no motivation to choose PVP from the long list of polymers disclosed in Cooke, to arrive at the present invention.

Applicant also offers that the skilled artisan would not have been motivated to look to Keusch to supply the alleged deficiencies in Cooke, namely, a cross-linked PVP hydrogel comprising, *e.g.*, 5 – 35% by weight PVP. This is because there is no mention in Cooke regarding the desirability to use PVP, much less the desirability to use cross-linked PVP, as presently claimed.

Finally, Applicant offers that Keusch’s disclosure is in a different field of endeavor (*i.e.*, medical electrodes) than Cooke (*i.e.*, adhesive skin patches for alleviating skin discomfort)—another reason why the skilled artisan would not have been motivated to look to Keusch to supply the alleged deficiencies in Cooke. Thus, because (i) Cooke teaches away from the claimed invention and (ii) the skilled artisan would not have been motivated to look to Keusch to supply the alleged deficiencies in Cooke, Applicant respectfully submits that the

rejection of the claims over Cooke and Keusch is based on the use of impermissible hindsight and should be withdrawn.

Second, the cited art would not have provided those of ordinary skill in the art with any expectation of successfully obtaining the claimed invention. Aside from the conclusory statement that the Examiner provides on page 9 of the Office Action, the Examiner has not set forth *any* factual or objective evidence as to why the skilled artisan would have the expectation of success in combining Cooke's compositions with Keusch's cross-linked PVP hydrogel. As the Examiner is well aware, an examiner's conclusory statement cannot form a basis for a *prima facie* case of obviousness. *In re Sang-Su Lee*, 277 F.3d at 1343-4.

Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness against the claimed invention because the art cited (i) does not suggest to those of ordinary skill in the art that they should make the claimed composition and (ii) does not provide one of ordinary skill in the art with a reasonable expectation of success. Therefore, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

The Rejection of Claims Under 35 U.S.C. § 103 Over Cleary In View of Keusch Should Be Withdrawn

Claims 1, 3 – 6, 12 – 16, 22, 24 – 27, 55, 56, and 59 – 69 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over Published U.S. Application No. 2003/0027833 ("Cleary") in view of Keusch.

According to the Examiner, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use Keusch's cross-linked PVP hydrogel, which comprises, *e.g.*, 5 – 35% by weight PVP, in Cleary's compositions and delivery systems for the administration of a local anesthetic agent. Office Action, page 10. Applicant respectfully disagrees with the Examiner.

First, there is nothing in the cited art that would suggest to those of ordinary skill in the art that they should use Keusch's cross-linked PVP hydrogel with Cleary's compositions—much less that if they tried, that it would have a reasonable expectation of actually working (*vide infra*). Cleary teaches that he can prepare a gel by using "a relatively smaller quantity of [a] monohydric alcohol . . . , *e.g.*, less than about 40 wt. %" Cleary, paragraph 22. There is no mention in Cleary about the desirability of cross-linking PVP, or of the use of already cross-linked PVP, to obtain his hydrogel. Instead, the gelling in Cleary

is strictly controlled by the amount of monohydric alcohol (*e.g.*, methanol and ethanol) that is used—not by cross-linking of the PVP—to obtain a gel. For at least this reason, the skilled artisan would not have been motivated to look to Keusch to supply the alleged deficiencies in Cleary, namely, a cross-linked PVP hydrogel comprising, *e.g.*, 5 – 35% by weight PVP. Applicant also offers that Keusch's disclosure is in a different field of endeavor (*i.e.*, medical electrodes) than Cleary (*i.e.*, compositions and delivery systems for administration of a local anesthetic agent)—another reason why the skilled artisan would not have been motivated to look to Keusch to supply the alleged deficiencies in Cleary. Applicant respectfully submits, therefore, that the rejection of the claims over Cleary and Keusch is based on the use of impermissible hindsight and should be withdrawn.

Second, the cited art would not have provided those of ordinary skill in the art with any expectation of successfully obtaining the claimed invention. Aside from the conclusory statement that the Examiner provides on page 11 of the Office Action, the Examiner has not set forth *any* factual or objective evidence as to why the skilled artisan would have the expectation of success in combining Cleary's compositions with Keusch's cross-linked PVP hydrogel. As the Examiner is well aware, an examiner's conclusory statement cannot form a basis for a *prima facie* case of obviousness. *In re Sang-Su Lee*, 277 F.3d at 1343-4.

Applicant respectfully submits that the Examiner has failed to establish a *prima facie* case of obviousness against the claimed invention because the art cited (i) does not suggest to those of ordinary skill in the art that they should make the claimed composition and (ii) does not provide one of ordinary skill in the art with a reasonable expectation of success. Therefore, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

Conclusion

Applicant respectfully submits that all claim rejections have been overcome and that all pending claims are now in condition for allowance, early notice of which is earnestly solicited.

Aside for the fees due for requesting an extension of time, no fee is believed to be due for this submission. However, if any fees are required for the entry of this paper or to avoid abandonment of this application, please charge the required fees to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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